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WO 1997/040766 A1 DE 004219939 A1
US 6228089 A US 6106464 A
US 5752962 A US 4979949 A

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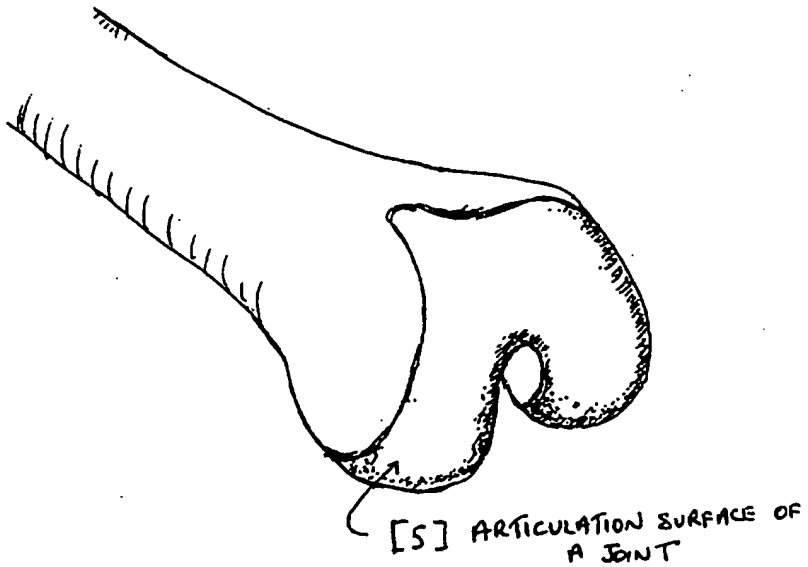
(54) Abstract Title
Referencing marker for use in computer assisted surgery

(57) A referencing marker 10 for use in computer-assisted orthopaedic surgery using computer-controlled automation (robotics). Preferably used in knee and ankle joint replacement surgery. The referencing marker may be designed using computer-aided drawing (CAD). It may comprise a base 6 which is a negative mould of the contour and geometry of all/part of the joint surface, a reference appendage 8 fixed in relation to the base which is used by the referencing apparatus of the robot to determine its position in relation to the joint, and a body 7 (which may have linear holes 12) to rigidly connect the base and reference appendage. May serve as a fiducial marker or guide for placement of fiducial pins. Computer-assisted manufacturing (CAM) may utilise the CAD design to produce a solid body. May also be used on the acetabulum of the hip joint, or glenoid of the shoulder joint.



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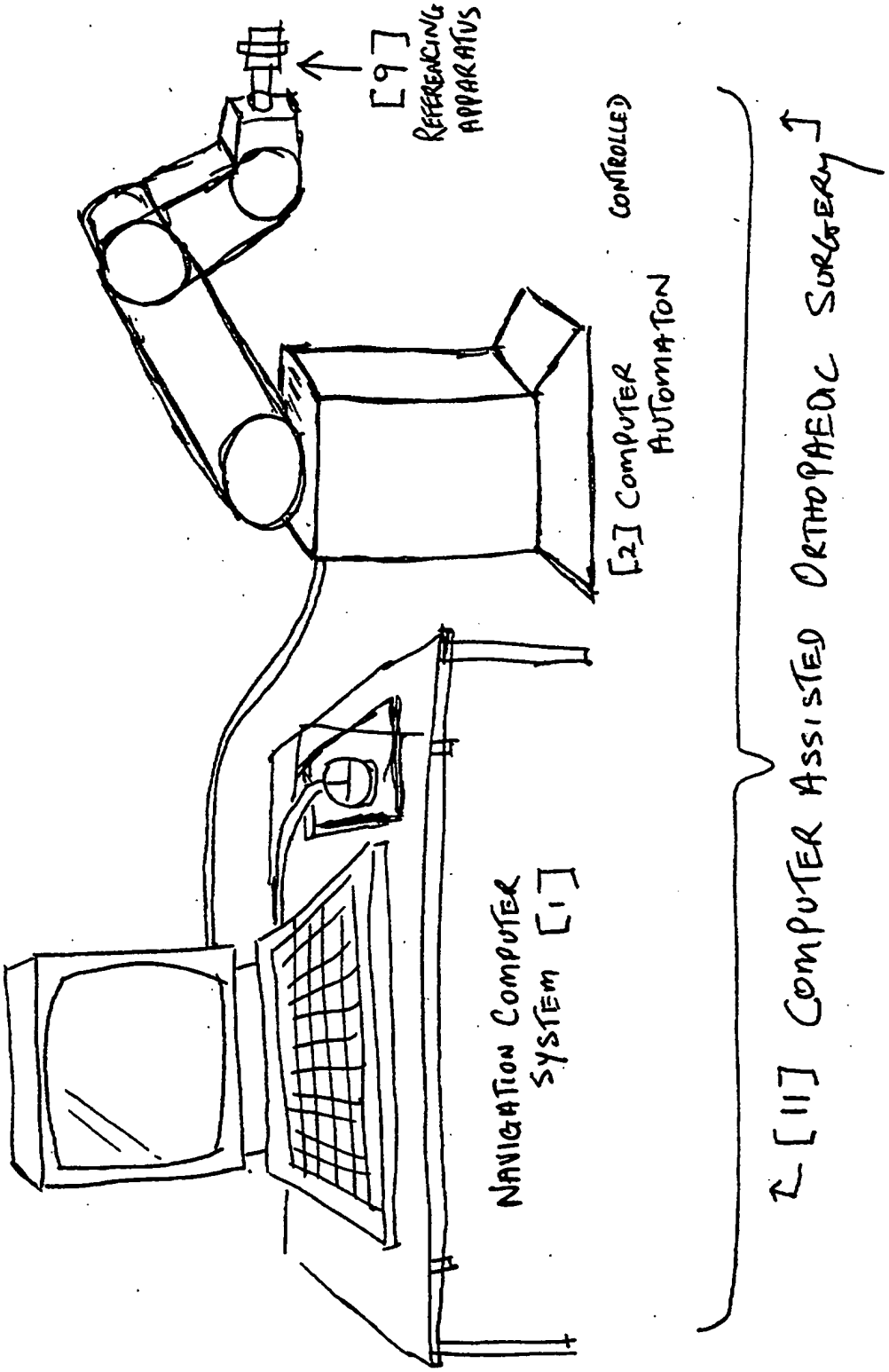
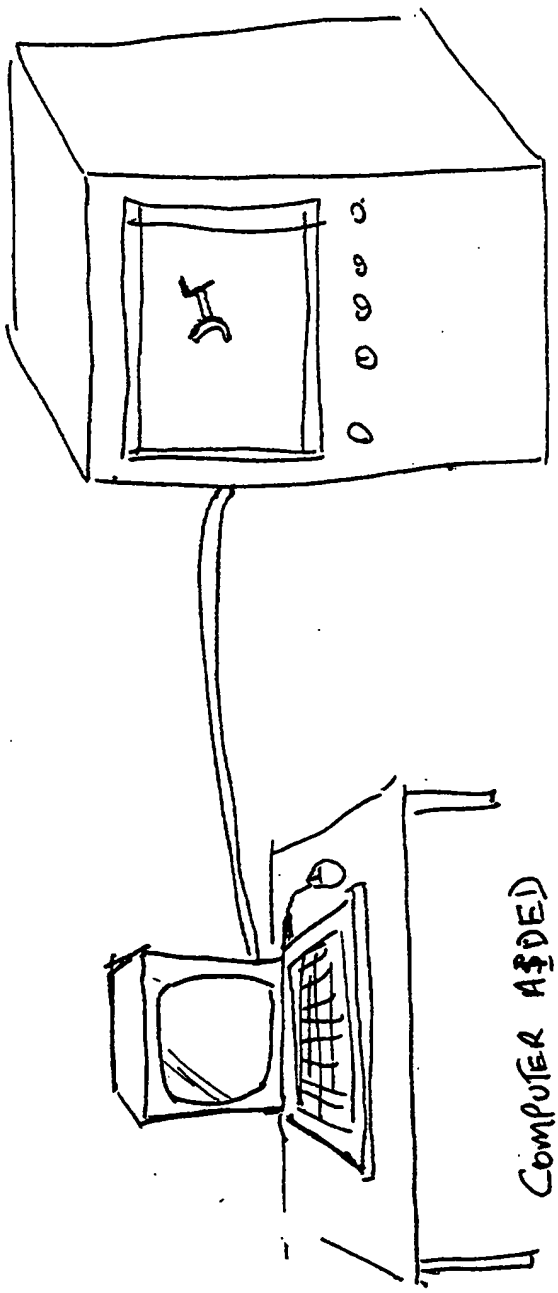
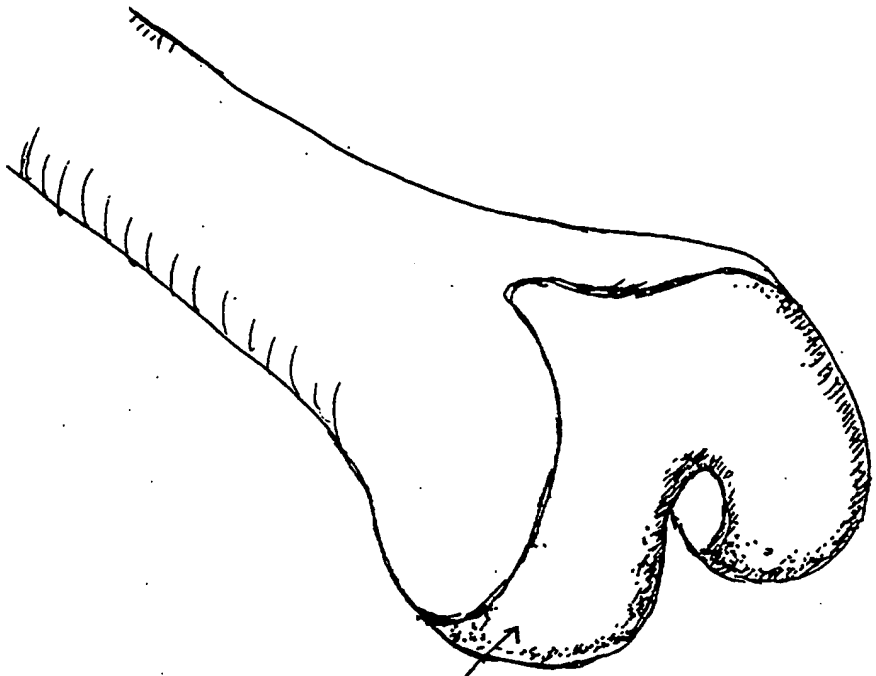
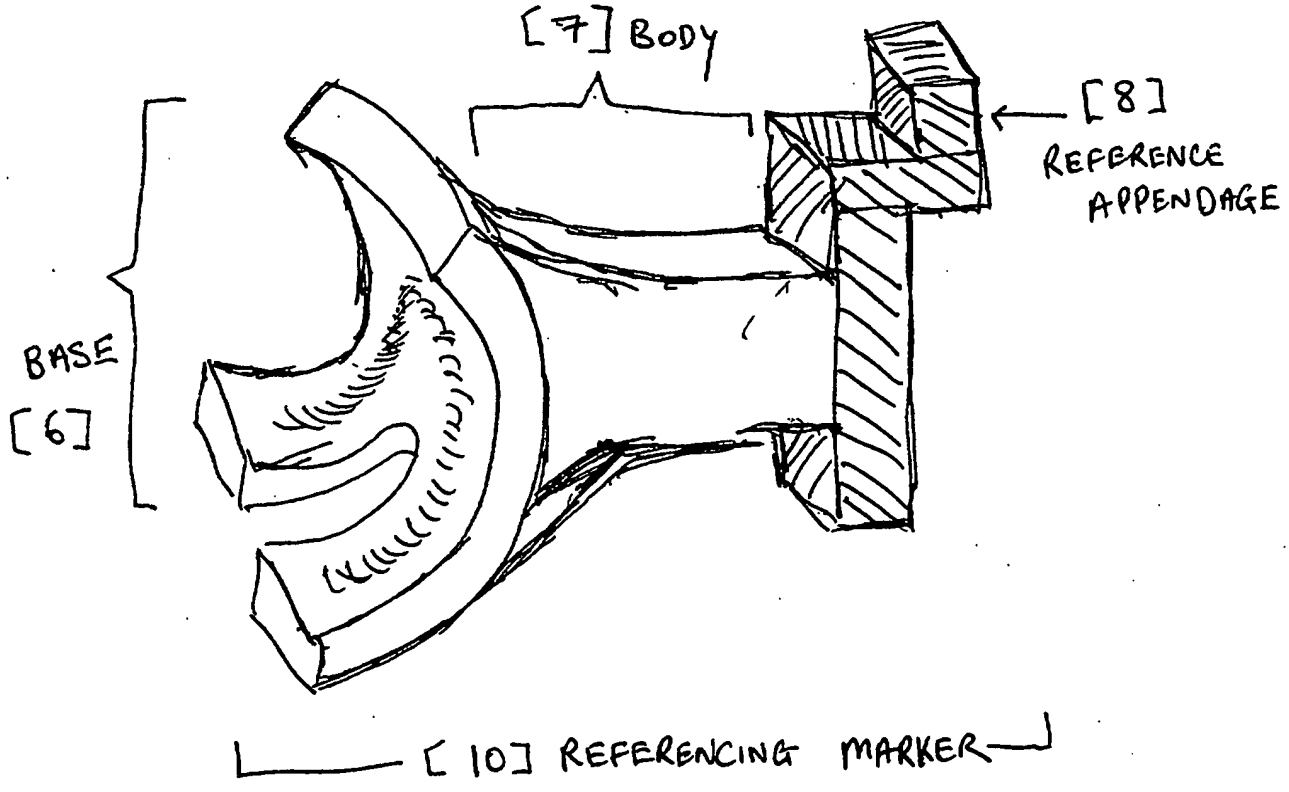

[9] REFERENCING APPARATUS
[2] COMPUTER AUTOMATION CONTROLLED
NAVIGATION COMPUTER SYSTEM [1]
[11] COMPUTER ASSISTED ORTHOPAEDIC SURGERY

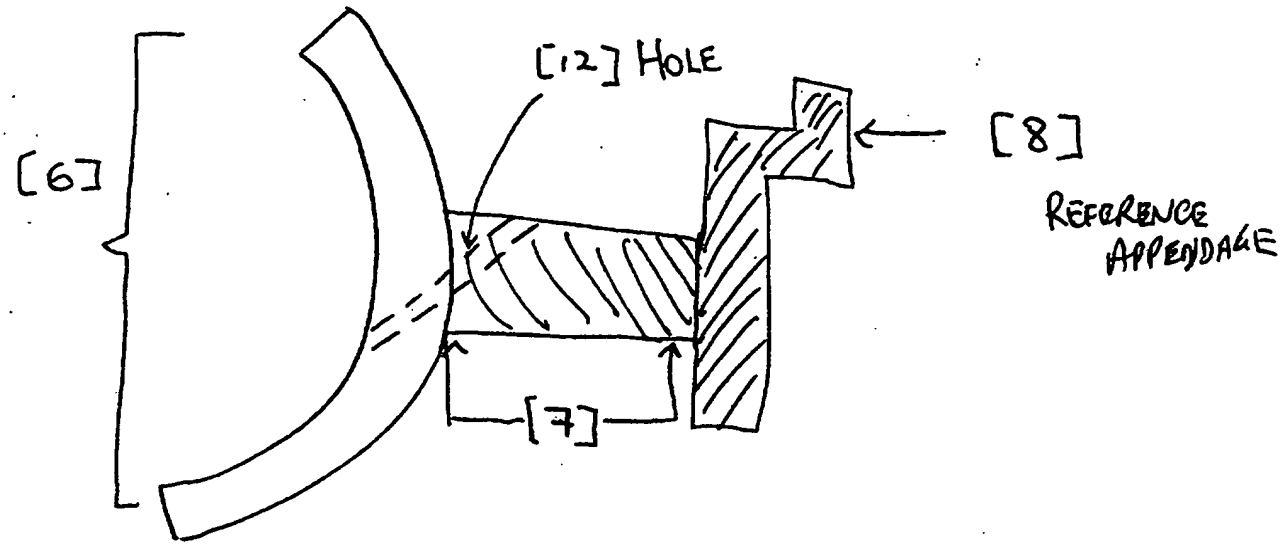


COMPUTER AIDED DRAWING SYSTEM CAD [3]

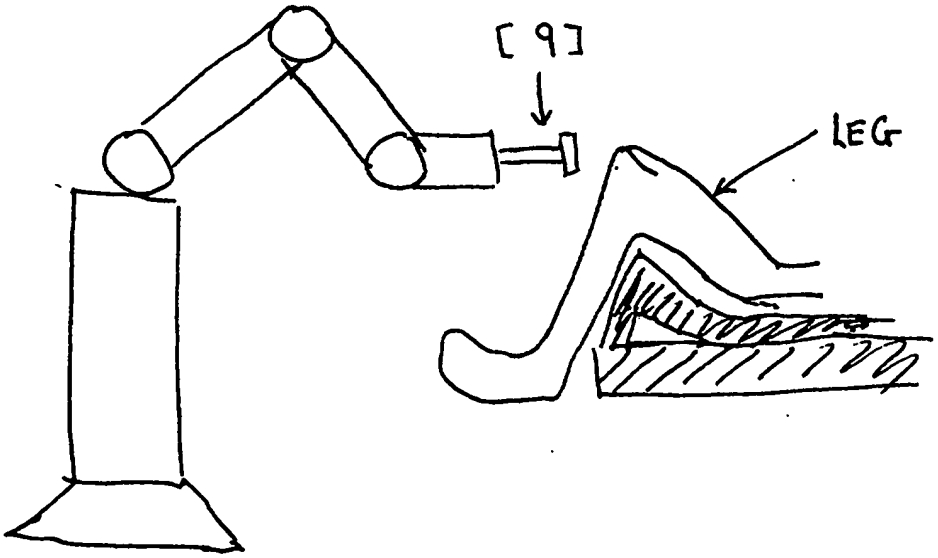
COMPUTER AIDED MANUFACTURING MACHINE [4]


[5] ARTICULATION SURFACE OF A JOINT


[7] BODY
[8] REFERENCE APPENDAGE
BASE [6]
[10] REFERENCING MARKER



~~FRONT~~ VIEW OF [10]
SIDE



[2]

As a result of the advanced developments in medical digital imaging technology (Magnetic Resonance Imaging Scan, Computer Assisted Tomograph Scan, and Ultrasound), it is now possible to acquire 3-Dimensional images of the internal human anatomy. This image can be of the skeleton (eg. knee joint, ankle joint or spine), internal bodily organs (eg. brain, liver, lungs), or vascular structures (eg: artery, vein). This technological development has provided superior means to appreciate internal anatomical structures in a 3 dimensional way. It also has provided an accurate means to determine the positional relations of different anatomical structures given a specific region of the body (eg. the position of the kidneys in relation to the liver) at the time of the scan. One specific use of the 3 dimensional digital data is that the images can be reconstructed and manipulated by surgical-planning computer programs and these images can be used for pre-operative surgical planning purposes. Such usage is well established in the field of Neurosurgery, where it is possible to use image data to precisely locate diseases such as tumours, and therapeutic radiation or biopsies procedures can be performed by minimally invasive technique.

The application of such digital image data technology has developed itself to be of importance in the field of Orthopaedic Surgery. The area of new development is in the use of Computer Controlled Automaton [2], such as a robot, to perform the tasks of cutting and drilling of the bone in Joint Replacement Surgery. It has been shown that automated devices can cut more efficiently and precisely than that achieved by the human counter-part. The result of this precise cutting provides a more accurate fit at the interface between the Prosthetic Joint Implant and the bone on which the implant adheres, thereby lowering complications such as implant loosening or accelerated wear of the implants. Other specific advantages of using Computer Assisted Surgery in Orthopaedics is that mechanical and physical data such as force vectors, centre of rotations, and anatomical axis can be calculated and be used to determine the optimal positioning of the implants; thus maximising the life of the implant.

In Computer Assisted Orthopaedic surgery [11], it is composed of a computer station (Navigation Computer System) and the computer controlled automaton [2], such as a robot. The Navigation Computer System is an intricate computer program which utilises digital information such as digital images, mechanical sensors, or light sensors, to determine spatial orientation of objects. It can exploit this function to

provide a "virtual vision" for machines like robots. It is by this that robots are able to perform defined tasks (eg. drilling, cutting, milling) on objects like a knee joint. Specifically in joint replacement surgery, a robot is able to resect accurately the articulation surfaces and surrounding bone of the joint to prepare this bone for the final insertion of the prosthetic implant. The prominent advantage of using computer robotic assistance in orthopaedic surgery over conventional techniques (ie. without a robot) is that the surgeon is able to pre-plan the cutting planes of the bone by the robot depending on the required orientation between the mechanical axis of the leg and the final position of the implant. In addition, the robot is able to achieve high precision and surface finish with its cutting planes. Prior to the robot's execution of its pre-programmed task, the Navigation Computer System (NCS) [1], which controls the robot, has to determine precisely the robot's spatial relationship in respect to the object on which the NCS [1] intends for the robot to perform the pre-programmed task.

The principal of positional referencing in Computer Assisted Orthopaedic Surgery, where a Computer Controlled Automaton [2] is employed, is explained in the following:

(1) In the virtual space, the 3-D digital image data of an object (eg. the femoral condyle of the knee joint) acquired from a MRI or CT, can be interpreted by the a NCS [1], which also controls all the movements of the robot. Within this space, the NCS[1] can orientate the spatial position of this object (femoral condyle) to a nominated defined reference point in this space. Following this, the spatial position of the CCA [2] is also digitally referenced to another defined point in this space. Using these two reference points, which can be adjustable by the surgeon, the NCS [1] can then define precisely where, and how the CCA (eg. robot) and the Object (bone) are orientated in relation to each other in this virtual space. It is by using this relative positional reference that the Robotic tasks are defined and later executed on the object. (Note: Instead of utilising a 3-Dimensional view of the CCA, the NCS that controls the CCA often simply uses one physical aspect (eg. a referencing apparatus [9] or a pointer on its robotic arm) of the CCA as the reference guide to identify the CCA s overall spatial positioning).

(2) In the physical space, the relative spatial orientation between the CCA and the object must precisely correspond to that which is registered by the NCS. Until the virtual space orientation and the physical space orientation between the CCA and the Object precisely corresponds, the CCA (which is controlled by the NCS) can then perform its programmed tasks upon the physical target object. One of the most important step, and

a rather difficult step, in the use of robots in Orthopaedic Surgery is the step of physically orientating the robot to the object on which it intends to perform its operation.

It is in the object of this invention to simplify this step of the said physical orientation between the robot and the bone surface. The uniqueness of this invention is that it is a physical device with a shape that is dependent on the required orientation needed between the robot and the joint surface. The surface on the device that attaches to the articulation surface of the joint bears the precise negative imprint of that contour and geometry of that surface, as predetermined by the MRI scan. It also has a reference appendage that is used by the referencing apparatus of the CCA [9] for orientation. Also in the uniqueness of this invention is that the reference appendage is positioned on this said inventive device in a fixed relation to the base of the device. This fixed relation between the reference appendage and its attachment surface[6] of the device is determined by the NCS[1], which itself has also determined the virtual spatial relation between the referencing apparatus[9] of the CCA[2] and the articulation surface of the joint.

An important principle that is exploited by this invention is that the physical details of the anatomical geometry of the articulation of a joint surface, as seen on the MRI scan, are unchanged by the physical task of surgical exposure of the joint. The articulation surface of the joint, unlike other parts of the anatomy, is unattached to any muscles or tendons. The joint is protected in a pocket of synovial fluid. This knowledge allows a crucial aspect of the said inventive device to be designed and made, requiring only details of an MRI scan, without needing to perform an additional operation of surgically implanting the fiducial marker prior to the final procedure.

In Computer Assisted Orthopaedic Surgery in which a Computer Controlled Automaton such as a robot is employed, a number of techniques have been devised in an attempt to make this procedure of physical orientation be rational, accurate, without unnecessary surgical incisions, minimal exposure to irradiation, and easy to perform. One common method relies on performing a addition surgical procedure under an anaesthetic for the placement of fiducial markers into the bone before the joint replacement surgery. The patient is then taken to the X-Ray department to have a CT scan for the registration of this fiducial marker. The patient is then to return to the operating theatre for the final operation of joint replacement surgery. The CT scan details are installed into the NCS, and the position of the joint in relation to the Fiducial Marker is

determined. One example is where the Computer Controlled Automaton has a position sensitive arm which then registers the position of the said fiducial marker and thus, the position of the joint can then be calculated by the NCS using the position of the Fiducial marker as a reference. The potential problems are that there are risks of infection from the surgical placement of the fiducial markers, and also risks associated with anaesthesia during the procedure. The Patient is also being exposed to ionising radiation from the CT scan through this process.

The disclosed invention is a Orthopaedic device which itself functions primarily as a fiducial marker, and it can also be used as a guide for the placement of fiducial markers. The application of the said device is to be used in Computer Assisted Orthopaedic Surgery where a Computer Controlled Automaton [2] is employed. The usage of the said inventive device avoids the necessity for the added operation of surgical placement of the fiducial markers, and therefore negating one source of infection. The said device is completely prepared for use before the operation and it is intended to be used intra-operatively. The usage of the said inventive device also prevents the patient from the necessity of exposure to ionising irradiation by the CT scan, as the design of this said device requires image data acquired from MRI scans. The usage of the said inventive device is accurate, because the surface of attachment of the said device to the joint surface is a precisely contoured conforming mould of the surface geometry of the articulation of the joint. This provides an unchanging and consistent interface to be used as a reference for the reference appendage of the device. The usage of the said inventive device is also accurate because the position of the reference appendage on this device is digitally defined by the NCS, and is set at a fixed relation to the articulation surface/mould interface of the joint.

The production of this inventive device utilises the advance technology available in the area of Computer Assisted Drawing software programs (CAD) [3]. There are many of these programs commercially available, and many of these are compatible with utilising digital images of MRI scan. One specific advantage of a CAD [3] program being able to manipulate MRI images is that the disclosed inventive device requires using a section of the surface of the joint to form the base surface of the final product. In addition, Computer Aided Manufacturing (CAM) [4], is another area of advance development. It utilises digital data technology to manufacture objects. It is able to utilise designs performed by most commercially available CAD programs. The commercial machines available presently are very compact, has a short manufacturing time, and can achieve an accuracy of +/-- 0.001 of an inch per inch of

manufacturing. It is therefore possible now to custom-make objects quickly and accurately. The said inventive orthopaedic device uses this existing technology (accuracy and speed) in the device's designing method and in its applications.

In the following, the precise method of designing this said device, its specific features and its method of use will be described in details;

Detailed Description:

The invention is an referencing marker[10], custom designed and fabricated for the use as a fiducial marker. The said referencing marker[10] can also serve as a guide for the placement of fiducial marking pins. To define the nature of this said referencing marker[10], an example of the method of designing the said referencing marker's[10] specific features and its method of application will be utilised.

The said referencing marker[10] is designed to be used as a fiducial marker in Computer Assisted Orthopaedic Surgery (CAOS) [11] in which a Computer Controlled Automaton (CCA) [2], such as a robot, is employed. The specific operations for which the said referencing marker[10] is intended are (1) Uni-Condylar Knee Replacement, and (2) Ankle Joint Replacement. In all cases, there are two opposing articulation surfaces requiring replacement. Therefore, there are two referencing markers[10] fabricated for each operation. Each said referencing marker[10] is designed specifically for an individual articulating joint surface[5].

Using an example of UKR, the following illustrates the method of design, fabrication, and use of the said referencing marker[10]. The description relates to the designing and fabrication of only one of the two articulation surfaces[5]. In practice, the procedure of design and fabrication is repeated for the opposite articulation surface .

In patients requiring a UKR by CAOS [11], an MRI scan is mandatory for pre-operative planning. The MRI Image is reconstructed in the Navigation Computer System (NCS) [1] using the digital image data. The NCS which also controls the Computer Controlled Automaton (CCA). The MRI image data is used by the NCS [1] in two ways:

(1) To assess the size of articulation surfaces, as well as the mechanical alignment of the joint. Using these data , the Surgeon determines the optimal size and positional placement of the final implants.

(2) To define, in digital format, the spatial relation between the referencing apparatus[9] of the CCA [2] to the articulation surface[5] of the joint on which the surgical procedure is proposed.

Using the 3-D digital data within the computer's virtual space, the user of the NCS [1] sets the positional reference of the articulation

surface of the joint [5] to the referencing apparatus[9] of the CCA[2]. This spatial relation is fixed and defined in a digital format. Using this digital data of the physical relation between the referencing apparatus[9] of the CCA [2] and the articulation surface of the joint [5], a technician or Surgeon then utilise a Computer Aided Drawing (CAD) device [3] to design the referencing marker[10] that fulfils this virtual space. The final solid product of this said referencing marker[10] will serve to physically orientate the position of the referencing apparatus[9] of the CCA [2] to the articulation surface[5] of the joint.

The said referencing marker[10] has the following features:

(1) The base [6]: which is the surface of the referencing marker[10] that contacts the articulation surface of the joint [5] on which the proposed automated procedure is intended. The specific feature of the base surface [6] is that it is a precise negative imprint of the distinct geometrical contour of the entire, or a section of, the articulation surface of the joint [5] on which the base [6] provides its attachment. The base [6] of the device conforms precisely to the contours of the articulation surface of the joint [5], thereby providing a stable and an unchanging interface upon coupling of the two surfaces. It is this unvarying interface upon which other aspects of the device is referenced.

(2) The Reference Appendage [8] (RA), which is used by the referencing apparatus[9] of the CCA[2] to determine its spatial relation to the target object [5] (ie the articulation surface). The positioning of this appendage[8] is pre-determined by the NCS [1] and has a defined relation to the base [6]. (Note: The NCS [1] has pre-determined the positional relation between the articulation surface and the CCA[9] referencing apparatus earlier.)

(3) A Body[7], which is of a solid construct that connects the RA[8] to the Base[6], and functions to maintain that pre-defined relationship between the RA[8] to the base[6].

(4) Hole/s[12]; linear uniaxial holes which traverses the body[7] and the base[6] in a direction which is in a fixed relation to the base[6]. The hole[12] is used as a guide for the placement of added fiducial pins.

Using the MRI image and the digital referencing information, the user of the Computer Aided Design (CAD) [3]tool can bring together the above 4 features. The NCS[1] has pre-determined the spatial relation between the referencing apparatus[9] of the CCA and the articulation surface of the joint[5], and this is stored in digital format.

The CAD[3] program is compatible with the digital format of MRI images. Using the MRI image, a representative section of the articulation surface[5] of the joint is extracted. This section forms the base[6] of the referencing marker[10] on the design. The size and shape of the reference appendage[8], which is sized to assemble with the referencing apparatus[9] of the CCA[2], is drawn. Using the pre-set relation by the NCS[1], the RA[8] is positioned accordingly in relation to its base[6]. A body[7] for the device[10] is then drawn to connect its base[6] to the RA[8]. The body[7] has to provide enough solid material to maintain this relation of the RA[8] to its base[6]. It is possible now to design linear holes[12] to perforate through the body[7] of the said device[10]. These holes[12] will have a defined relation to the base[6]. The function of these hole/s[12] are used for guidance for the placement of additional fiducial pins, if needed.

The importance of the MRI is highlighted here; only MRI images can feature the cartilage and bony contour of the articulation surface, whereas the CT scan can only demonstrate the bony details of the articulation surface. The object of this invention is to have an exact and precisely conforming interface between the articulation surface[5] and the base[6] of the device. The articulation joint surface is composed of both cartilage and exposed bone. It is required, therefore, that only MRI images can be used for the purpose of CAD designing for the base of the said referencing marker[10].

Once the final shape of the referencing marker[10] is completed on the CAD, the data file of the design is transferred into a Computer Assisted Manufacturing (CAM) [4] machine in which the solid version of the said referencing marker[10] will be fabricated. The CAM machine has an accuracy of +/-- 0.001 of an inch per inch of manufacturing. There are various commercial machines built for the purposes of manufacturing CAD designed items. (eg., PatternMaker by Solid Scape Inc, another example is the ThermoJet by 3-Dimensions). The referencing marker[10] is generally made of a rigid thermoplastic material, but any material which can provide a substantial rigidity is acceptable. The final solid device is then carefully packaged and sterilised using gamma radiation for intra-operative use.

During the operation, the patients knee[13] is appropriately positioned on the operating table and the skin is sterilised. The surgeon will then commence the procedure of the surgical exposure of the knee. Once appropriate exposure of the joint is achieved, the said referencing

marker[10] is taken out of its sterile packaging and its base[6] is carefully positioned onto the joint surface. Once precise moulding of the base[6] to the articulation surface[5] of the joint is achieved, the CCA[2] with its referencing apparatus[9] is now brought into its final position utilising the Referencing Appendage[8] on the said device. The CCA[2] itself has a Reference apparatus[9] which assembles with the Reference appendage[8] of the said device for positioning. Once the position of the CCA[2] is fixed and stabilised, the said device[10] can now be disassemble from the referencing apparatus[9] of the CCA, and the device[10] can now be removed from the articulation surface[5] of the joint. The CCA[2] and the articulation surface[5] of the joint is now in an identical relation to that which is predetermined by the NCS[1] in its virtual space. The automated procedure by the CCA is now ready to commence under the control of the NCS. This process is then repeated on the opposing articulation surface using yet another custom-made referencing marker[10] that is specific to its articulation surface geometry.

The embodiment of this invention includes:

(1) The specific features of the said referencing marker [10] as described above:

- The Base[6]: which is an exact negative imprint of the articulation surface geometry of the joint.
- The Reference Appendage[8], which has a defined relation to the base (verified by digital format), and which is utilised by the referencing apparatus [9]of the CCA[2] to orientate its position to the target object.
- A Body[7], which provides a rigid connection between the reference appendage[8] and its base[6].
- Hole/s[12] through the body[7], which serves as guide holes for placement of fiducial marking pins.

(2) The Specific Function of the said referencing marker[10]:

- The said referencing marker[10] serves as a removable fiducial marker for the positional referencing for the referencing apparatus[9] of the Computer Controlled Automaton Unit[2] onto the said articulation surface[5] of the joint.
- The said device[10] serves as a guide for the placement of fiducial marking pins. The direction of the holes have a defined relation to the base[6].

(3) The Specific Application:

- This said referencing marker[10] is specifically designed to be used in Computer Assisted Orthopaedic Surgery[11] where a computer controlled automaton[2] is employed.
- The operations for which the said device is designed are (1) Uni-condylar Knee Replacement and (2) Ankle Joint Replacement.

(4) The Specific Objectives of this invention:

- Provide a reliable fiducial marker for the CCA unit in its application in UKR and AJR in CAOS.
- To provide a guide for the placement of fiducial pins.
- To avoid unnecessary ionising radiation for the patient by CT Scanning.
- To avoid an unnecessary procedure of surgical insertion of fiducial markers into the bone prior to the final joint replacement surgery, thereby minimising trauma and risks of infection for the patient.
- To provide a technique in which fiducial markers are placed intra-operatively, thereby shortening the overall time of the procedure.
- To provide a simplistic method of positional orientation between the CCA unit and the articulation surface of the joint.

The following are the 4 articulation surfaces that are intended for use with the said fiducial marker.

In Uni-condylar Knee Replacement;

(1) The convex Medial Femoral Condyle
(2) The slightly concave Medial condyle of the proximal tibia

In Ankle Joint Replacement:

(1) The Mortise, made up of the distal inferior surface of the distal tibia, the medial surface of the lateral malleolus, and the lateral surface of the medial malleolus of the distal tibia.
(2) The talar dome of the talus bone.

Claims:

What is claimed is:

(1) A referencing marker[10] designed for use in Computer Assisted Orthopaedic Surgery[11] where a Computer Controlled Automaton (CCA) [2] is employed.

(2) A referencing marker [10] of claim (1) wherein the intended operations of use by the said referencing marker [10] are one; Uni-condylar Knee Replacement Surgery, and two; Ankle Joint Replacement Surgery.

(3) A referencing marker [10] of claim (2) which is distinctly designed utilising Computer Aided Drawing (CAD) [3].

(4) A referencing marker [10] of claims (1-3) wherein the specific features of the said referencing marker [10] has;

- A Base[6]; which is a precise negative mould or imprint of the contour and distinctive geometry of the articulation surface[5] of the joint, or part of it, on which the surgical procedure is proposed.
- A Reference Appendage[8], which has a fixed and defined relation to its base[6], and is used by the referencing apparatus[9] of the Computer Controlled Automaton[2] to determine its positional relation to the target object[5] (eg. articulation surface of the joint).
- A body[7], which provides a rigid fixation of the said Reference Appendage[8] to its Base[6] , and which maintains their said fixed positional relation.
- Linear holes[12], which traverse through the said body[7], which provides guidance of placements of additional fiducial pins. These holes have a fixed and defined relation to its base[6]. These relations are predetermined during the design process with the CAD [3] program.

(5) A referencing marker [10] of claim (1-4) wherein the function of the said referencing marker[10] is to serve as a fiducial marker which provides a physical spatial verification for the referencing apparatus[9] of the Computer Controlled Automaton[2] unit for positional orientation.

(6) A referencing marker [10] of claim (5) wherein the pertinent feature of the base of the said referencing marker[10] is that it has a precise negative imprint of the anatomical contour and geometry of the articulation surface[5] of the joint on which the intended operation by the CCA[2] is proposed.

(7) A referencing marker [10] of claim (6) wherein the referencing appendage[8] of the said referencing marker[10], which is utilised by

the referencing apparatus[9] of the CCA for positional referencing, has a fixed and defined positional relation to its base[6].

(8) A referencing marker [10] of claim (7) wherein the reference appendage[8] is physically attached in a fixed relation to the base[6] through its body[7].

(9) A referencing marker [10] of claim (8) wherein the body[7] of the said referencing marker[10] is constructed of a rigid solid construct.

(10) A referencing marker [10] of claim (9) wherein there are linear holes[12] designed to pass through its body[7] and which have a fixed relation to its base[6]. These holes are designed for the purpose of guidance for placement of fiducial marking pins.

(11) A referencing marker [10] of claim (10) wherein upon completion of the designing process, the digital image data of the CAD drawing of each individual referencing marker[10] is transferred to a Computer Assisted Manufacturing machine[4] where the said referencing marker [10] can be built.

(12) A referencing marker [10] of claim (11) wherein it [10] is also used as a guide for the placement of fiducial marking pins.

(13) Although the operations of use of the said referencing marker [10] of claim (12) is mainly intended for use in Uni-condylar Knee Replacement Surgery or Ankle Joint Replacement Surgery using Computer Assisted Surgery technology, it is not exclusive of the said referencing marker [10] to be used in the knee or the ankle joint. The said referencing marker[10] of claim (12) can also be used on the Acetabulum of the Hip joint or the Glenoid of the Shoulder Joint.

Application No: GB 0129384.4 **Examiner:** Stephanie Parry
Claims searched: 1 to 13 **Date of search:** 2 April 2002

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.T): A5R (RAT)

Int Cl (Ed.7): A61B: 5/00, 5/05, 5/055, 5/103, 5/107, 19/00; A61F: 2/46, 2/50, 2/76

Other: ONLINE: EPODOC, WPI, JAPIO

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
A	WO 97/40766 A1	(UNIVERSITY OF FLORIDA) Figs	-
A	US 6228089	(WAHRBURG) Figs	-
X	US 6106464	(BASS) Figs, col 3 lines 8-15, 23-31, col 4 lines 22-26, 35-39, col 6 lines 24-28, 51-59, col 7 lines 21-25, col 8 lines 19- 20	1, 2, 5
A	US 5752962	(D'URSO) Figs	-
X	US 4979949	(MATSEN) Figs, especially 15-18, col 4 line 56 to col 5 line 40, col 6 lines 2-5, col 10 lines 18-39, col 21 lines 17-18, 43-45	1, 2, 5
X	DE 4219939 A1	(RADERMACHER) Figs, especially 13a to 13d and 15a, part 4 and WPI Abstract Accession No 1994-000545/46	1 to 3, 5

X Document indicating lack of novelty or inventive step
Y Document indicating lack of inventive step if combined with one or more other documents of same category.
& Member of the same patent family
A Document indicating technological background and/or state of the art.
P Document published on or after the declared priority date but before the filing date of this invention.
E Patent document published on or after, but with priority date earlier than, the filing date of this application.